Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University
SESSION: Planning/Monitoring SIG Break-Out

Session Information	**Date: May 31, 2007** **Time: 11:00 a.m.–12:30 p.m. PDT** **Presenter/Lead: CTMS Lead: John Speakman, Meg Gronvall** **DSIC Lead: Laura Bradley, Jack London** **Facilitator: Mark Adams** **Scribe: Susan Varghese**
Executive Summary	The Data Sharing and Intellectual Capital (DSIC) Workspace representatives presented a summary report (see Table 1) on policies related to data sharing. The report was synthesized from issues captured during Day 1 break-outs for Planning/ Monitoring, Study Conduct, and Reporting/ Sharing. The Interoperability Special Interest Group (SIG) will inherit the policies from the other SIGs. Instead of focusing on each individual tool, the DSIC Team focused on the data outcomes from these tools because data sharing was what would be affected by DSIC policies. The Summary addressed issues of intellectual property (IP) value, data sensitivity, Institutional Review Board (IRB) restrictions, and Sponsor restrictions, and categorized the policies based on high, medium, and low impact. The Summary concluded that buy-in from various stakeholders was critical to the effective development of data sharing policies and that it was important to communicate that data sharing was about gaining data accessibility. DSIC should leverage policies within other programs (e.g., Specialized Programs for Research Excellence [SPORE]). The top priority for DSIC would be to garner IRB buy-in and develop policies concerning IRB restrictions.
Discussion	• The group used DSIC's Privacy/ Intellectual Capital Terms and Conditions Decision Tree as the framework for discussion (see Exhibit 1, attached below) on the DSIC issues relevant to each of the SIGs, namely, Planning/Monitoring, Study Conduct, Reporting/Sharing, and Interoperability. • The group agreed that DSIC issues were not about individual tools but the data outcome from these tools, i.e., data sharing issues. Data were therefore categorized into protocol , patient, or data related as shown on the top row of the Table (Exhibit 2), titled, "DSIC Framework for Facilitation of Data Sharing in caBIG™ Applications and Beyond" (attached below). Issues relevant to data sharing were synthesized and presented in the table. • Each data group was categorized into three levels (high, medium, low) based on intellectual property (IP) value, data sensitivity, IRB restrictions, and sponsor restrictions. These classification may not be mutually exclusive, i.e., in some cases, the issue may vary in degree from low to high depending on the type and ultimate use of the data. • The goal for DSIC is to create an environment in which all stakeholders (researchers, patients, sponsors) would be able to say "I can share if we agree on these policies" instead of "I cannot share my data." • Generating policies will involve developing clear communications regarding each issue and obtaining buy-in from the leaders in the community. • "Sharing data" is simply enabling accessibility to data. Communicating that the goal is to gain "accessibility" will be central to obtaining the buy-in of the leaders. "Sharing" has a coercive connotation whereas "accessibility" has an open connotation—stakeholders will relate better to gaining accessibility. • One approach for promoting data sharing is to use it as a metric for awarding grants to clinical

researchers.

- Data sharing policies should address not just NCI-sponsored trials but also all clinical trials. For example, at University of Michigan, 20 percent of trials are internally sponsored.
- Adverse Events should be separated from Response Outcome/ Evaluation because policies related to adverse events are complex in terms of who sees what and when.
- User authentication should be considered as part of the framework.
- Scientific integrity is an issue that will need to be addressed. If data are shared, they should have associated metadata so that they provide a layer of quality control but also ensure that researchers do not perform inappropriate analysis.
- DSIC should leverage other programs with policies already in place; e.g., the SPORE community.
- Developing policies concerning protocol abstraction and administration would be the easiest issue to tackle first to demonstrate early success.

Next Steps

- The first priority for DSIC is to develop policies concerning IRB restrictions. Building IRB support and buy-in is critical in enabling successful data sharing. If DSIC can get Office for Human Research Protections (OHRP) and Alliance for Human Research Protection (AHRP) buy-in, then it will be easier to get IRB to comply.
- The next priority for DSIC will be to focus on policies concerning IP value.

Attendees

	Last Name	First Name	AFFILIATION
1.	Adams	Mark	Booz Allen Hamilton
2.	Andonyadis	Christo	NCI Center for Bioinformatics
3.	Arzoomanian	Rhoda	University of Wisconsin – Madison
4.	Bradley	Laura	Oregon Health & Science University
5.	Brock	Elaine	University of Michigan
6.	Chahal	Amar	Velos, Inc.
7.	Courtney	Paul	Dartmouth/Norris Cotton Cancer Center
8.	Covitz	Peter	NCI Center for Bioinformatics
9.	Deering	Mary Jo	NCI Center for Bioinformatics
10.	Elcombe	Sharon	Mayo Clinic Cancer Center
11.	Grama	Lakshmi	Office of Communications and Education, NCI
12.	Gronvall	Meg	Booz Allen Hamilton
13.	Hetrick	Virginia	Academics
14.	Joyce	Niland	City of Hope National Medical Center

	15.	Lanese	Bob	Case Western Reserve University
	16.	London	Jack	Thomas Jefferson University / Kimmel Cancer Center
	17.	Loose	David	BLCPro
	18.	Mathew	Jomol	Dana-Farber Cancer Institute
	19.	Nosowsky	Rachel	University of Michigan
	20.	Rickman	Diane	Booz Allen Hamilton
	21.	Smith	Daniela	Booz Allen Hamilton
	22.	Speakman	John	NCI Center for Bioinformatics
	23.	Varghese	Susan	Booz Allen Hamilton
Attachments	1. DSIC Privacy/ Intellectual Capital Terms and Conditions Decision Tree (Exhibit 1) 2. DSIC Framework for Facilitation of Data Sharing in caBIG™ Applications and Beyond (Exhibit 2)			

Exhibit 1: Decision Tree for Privacy/Intellectual Capital Terms and Conditions

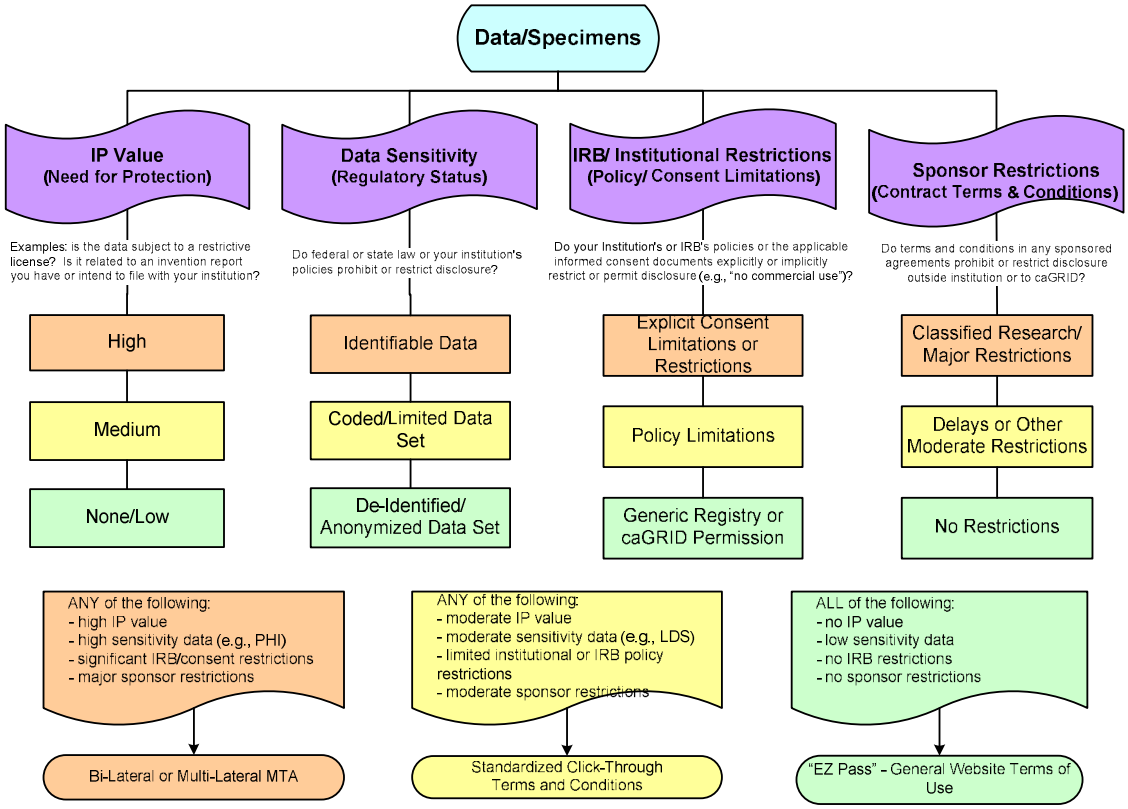

Exhibit 2: DSIC Framework for Facilitation of Data Sharing in caBIG™ Applications and Beyond

Framework Consideration	Protocol Abstraction	Protocol Administration	Basic Patient Demographics	Baseline Characteristics	Treatment/ Intervention	AEs	Response/ Outcome/ Evaluation
IP Value (Need for Protection from Institution/PI Perspective)	Some portion of protocol abstraction is completely public (e.g., anything registered at www.clinicaltrials.gov); some portion may be highly proprietary.	TBD (use CTEP data elements to develop a use case?)			Value increases with aggregation. THIS IS WHERE THE PI LIVES/WHERE NEW PROTOCOLS ARE DEVELOPED.	Value can be very high, particularly in correlative studies.	
Data Sensitivity (Privacy/ Security Considerations – Legal/ Regulatory)			Sensitivity depends on level of deidentification, aggregation, validation, and security. May be influenced by specific limitations on redisclosure promised in IC documents.				
IRB/Institutional Restrictions (Human Subjects Considerations – Ethical)	[patient-centered disclosure considerations]		Sensitivity depends on restrictions in consent forms, local IRB ethical considerations, etc.; reduced by level of deidentification, validation, aggregation, security. It is increased for certain populations (based on characteristics/risk factors, e.g., BRCA+), at least in applications capturing baseline characteristics and treatment/intervention data.				
Sponsor Restrictions (Grant or Contract Terms and Conditions)	Varies by sponsor, study phase, data elements made available, etc.	TBD (use CTEP data elements to develop a use case?)	Varies by sponsor, study phase, data elements made available, etc.				

Parking Lot (for DSIC)

- Academic credit (what's the incentive to share)
- Funding incentive (how do PIs differentiate themselves)*
- Personalized medicine

Important Considerations

- Who (who has access, who has authorization to disclose, etc.)
- When (when does disclosure occur; are there delays in disclosure)
- Quality control (metadata issues)

Goals

- Identify subsets of data in each category that should always be considered "green"
- Identify subsets of data that can't be green but can be at least yellow
- Identify timing when even sensitive data can be shared